REMARKS/ARGUMENTS

Election

Applicants' counsel wishes to thank the Examiner for speaking with applicants' counsel on April 13, 2006 and May 30, 2006 regarding the restriction requirements. While no agreement was reached, applicants' counsel gained a greater appreciation for the Examiner's position.

In response to the Restriction Requirement, the applicants elect Group I with traverse. Group I includes claims 1-11.

Regarding the form of extract in claim 3, applicants elect "lyophilized powder" with traverse.

Regarding the "agent for adjusting" in claim 5, applicants elect "tonicity" with traverse. Since this is the elected agent for adjusting, the specific agent selected is sodium chloride (see claim 6).

Regarding the nasal administration form in claim 11, applicants elect nasal drops with traverse.

Applicants understand that the restriction requirements regarding restriction of Groups I through IV is based on the Examiner's position that original claim 1 "is anticipated by or obvious over Gupta et al." Claim 1, as amended, now claims:

1. An anticonvulsant pharmaceutical composition for nasal administration having binding affinities for the receptor sites *viz.* GABA-A agonist site, Glutamate- AMPA site, Glutamate-Kainate site, Glutamate-NMDA agonistic site, Glutamate-NMDA glycine (strychnine insensitive) site and Sodium channel (site 2), consisting essentially of:

   i. an extract of the pericarp of the fruit of *S.trifoliatus*, comprising from 0.001 to 1.0 (% w/v) of hederagenin, and

   ii. at least one pharmaceutically acceptable additive.

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Thus, claim 1, as amended, excludes from the claimed composition extract from plants other than *S.trifoliatus*. Unlike the claimed invention in amended claim 1, the composition disclosed in Gupta et al. requires extract from *Emblica officinalis* to provide a synergistic effect with extract from *S.trifoliatus*. As noted in the specification of the present application at page 9, the composition disclosed in Gupta et al. "is associated with the following shortcomings, viz.

a) involves the utilization of two active principals, viz. *S.trifoliatus* and *Emblica officinalis*

b) involves a lengthy extraction and soaking process of the active principals taking at least 7 days

c) use of nitrogen gas throughout the period of soaking and extraction

d) use of a number of pharmaceutically acceptable additives, and in particular

e) use of alum, which is a known irritant and a corrosive chemical in the composition

all of which taken in conjunction not only lead to increase in the cost and time of manufacture but also renders the composition less safe."

The specification of the present application states at page 9 that there "exists a need, therefore, for a method of treatment of migraine, which addresses the shortcomings of the existing methods and which, moreover, is safe, less expensive and is convenient, which forms the objective of the present invention."

In view of the forgoing, it is respectfully submitted that claim 1 is patentable over Gupta et al., and therefore there is a unity of invention.

Gupta et al. does not teach 0.001 to 1.0 (%w/v) of hederagenin present in the extract that is combined with at least one pharmaceutically acceptable additive to form the composition claimed in claim 1. Applicants have discovered a novel and non-obvious composition for nasal administration that does not require an extract from a plant other than *S.trifoliatus*, and in which the extract has a specific concentration of 0.001 to 1.0 (%w/v) of hederagenin, and in

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combination with at least one pharmaceutically acceptable additive, forms the composition for nasal administration.

In view of the foregoing, applicants respectfully submit that pending claims 1-11 are in condition for allowance, and that the restriction requirements regarding Groups I through IV and election of species regarding pending claims 1-19 be withdrawn as there is clear unity of invention. Similarly, new claim 20, which depends from claim 1, is in condition for allowance.

Because the pending claims have a single general inventive concept (see PCT Rule 13.1), and there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features (see PCT Rule 13.2), the restriction requirements should be withdrawn. See MPEP 1850, which states in part: "If the independent claims avoid the prior art and satisfy the requirement for unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims." As noted in MPEP 1850 III A: "The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product; . . ."

It is further noted that there was no determination by the European Patent Office of a lack of unity of invention in the corresponding PCT application. See the PCT Written Opinion mailed July 23, 2004 in the corresponding PCT Application No. PCT/IN03/00289, a copy of which was submitted on February 28, 2005 in the present U.S. application.

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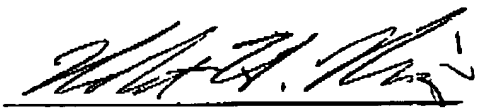
Conclusion

The Applicant reserves the right to prosecute the non-elected claims in one or more divisional applications in the event the non-elected claims are not examined in the present application. Should it be deemed necessary to facilitate prosecution of the application, the Examiner is invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: May 30, 2006

By: 

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